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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,632	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3006/JJC	4659
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BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			EXAMINER LEWIS, KIM M	
			ART UNIT 3772	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/725,632

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Kim M. Lewis

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/29/07 and the interview held 1/30/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, 14, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 14, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 1/30/08
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Detailed Action

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 11/29/07 has been entered.

2. As requested in the submission, claims 1 and 22 have been amended, claim 23 has been newly entered, and claims 4-5, 13, 15-20 have been cancelled.

3. Claims 1-3, 6-12, 14, 22 and 23 are pending in the instant application.

Election/Restrictions

4. The species are independent or distinct because they are alternative embodiments and are not disclosed as capable of use together. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, since there are no drawings present in the application for claims 23, it is not clear to the examiner if generic claims are present.

Art Unit: 3772

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence

Art Unit: 3772

or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. During a telephone conversation with Justin Cassell on January 31, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-3, 6-12, 14, and 22. Affirmation of this election must be made by applicant in replying to this Office action. Claim 23 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

Art Unit: 3772

time the application was filed, had possession of the claimed invention. More specifically, "*the discrete facing layer having an uninterrupted thickness*" denotes new matter since neither the written specification nor drawings provide support for such a feature. Applicant should note that the apertures in the facing layer prevent the thickness from being uninterrupted.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 1, applicants' recitation of "a skin adherent facing layer **consisting of** " (emphasis added) is in conflict with "the silicone gel layer including a skin treatment agent selected from the group consisting of aloe vera and petroleum jelly".

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3772

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-3, 6-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2006/0129081 ("Binder et al.") in view of U.S. Patent No. 6,207,875 ("Lindqvist et al.") and U.S. Patent No. 6,485,776 ("Janusson et al.").

17. As regards claim 1, Binder et al. disclose a wound dressing in the form of a gel wrap that substantially discloses applicants' invention. More specifically, Binder et al. disclose a skin adherent facing layer (5) comprising a hydrophobic discrete and resilient sheet-like layer of silicone gel (para. 0027). As can be seen from Fig. 9 and read from para. 34, perforations are solely provided in the silicone gel layer, between its generally continuously planar outermost surfaces in order to direct moisture away from the user. Binder et al. fail to teach the

Art Unit: 3772

silicone gel is being cross-linked and includes a skin treatment selected from the group consisting of aloe vera and petroleum jelly.

18. Lindqvist et al. disclose a wound dressing comprising a cross-linked layer of silicone gel, namely polyorganosiloxane, the same silicone gel disclosed and used in Binder et al. It is well known to cross-link materials in order to impart a particular characteristic to the material. Thus, it would have been *prima facie* obvious to one having ordinary skill in the art to substitute the cross-linked silicone gel of Lindqvist et al. for the silicone gel of Binder et al. because of the well known added physical properties provided by cross-linking.

As to the addition of aloe vera or petroleum jelly, Janusson et al. disclose a medical device for use on the skin comprising a silicone elastomer layer that includes one or more skin treatment agents blended into the silicone elastomer, for example, Vaseline and aloe vera.

In view of Janusson et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to agents such as Vaseline and aloe vera to the silicone elastomer gel of Lindqvist et al. in order to treat the skin while the device is being worn.

Regarding claim 6, as can be seen from Fig. 9, Binder et al. disclose apertures that are generally circular.

Regarding claim 7, as can be seen from Fig. 9, Binder et al. disclose the wound dressing in the form of a wrap according to claim 1, wherein the apertures are generally uniform in shape.

Art Unit: 3772

Regarding claim 8, as can be seen from Fig. 9, Binder et al. disclose apertures that are generally equally spaced from one another.

As regards claim 2, 3 and 9-11, the modified device of Binder et al. substantially disclose the invention as claimed except that the plurality of apertures are defined in a pattern varying in number per unit area according to their location relative to a center axis of the silicone gel layer, that the plurality of apertures are defined in a pattern varying in size according to their location relative to a center axis of the silicone gel layer, that the pattern of the apertures comprises alternating apertures of at least two different sizes, that the apertures have two different sizes, the first size being larger than the second size and the apertures of the first size being bordered by the apertures of the second size, and that the apertures of the second size are bordered by the apertures of the first size.

Binder et al., however, disclose in para 0037 that "the perforation density (i.e., the number and/or size of the perforations in the gel layer, may vary according to the particular requirements of the intended use of the bandage". It is also known from Lindqvist et al., that the absorption rate of the dressing can be varied by varying the density of the hole pattern and the size of the holes, and that the hole pattern increases the flexibility of the dressing (col. 4, line 67-col. 5, line 5). Thus, in light of the disclosure in Binder et al. and in view of Lindqvist et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the arrangement of the holes and size of the

Art Unit: 3772

holes in the silicone gel, in order to achieve a desired effect (e.g., increase the absorption rate, increase flexibility, etc.).

As regards claim 14, Binder et al. disclose the use of perforations and/or grooves to aid in directing moisture (para.0034), thereby inherently disclosing the wound dressing according to claim 1, wherein the silicone gel layer has regions of varying thickness, particularly in the grooves.

19. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Binder et al. in view of Lindqvist et al. and Janusson et al. as applied to claim 1 above, and in further view of U.S. Patent No. 6,461,467 ("Blatchford et al.").

As regards claim 12, Binder et al., Lindqvist et al. and Janusson et al. all fail to teach the silicone gel layer has a progressive increase of tackiness extending from a central portion to a border portion.

Blatchford et al., however, disclose a medical dressing with two adhesives, wherein one adhesive has greater adhesive tack than the other so as to allow the dressing to adhere better to the skin at certain locations, for example, the periphery of the dressing, and adheres less to the portion which contacts the wound (abstract, col. 2, lines 12-20 and lines 31-38).

In view of Blatchford et al., it would have been obvious to one having ordinary skill in the art to provide the modified dressing of Lindqvist et al. with a silicone gel layer having two different tacks, in order to allow the center portion of the dressing which contacts the wound to adhere less than, for example, the

periphery of the dressing to which surrounds the wound. This will allow the dressing to firmly adhere to the skin, but only at areas surrounding the wound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

